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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,343	09/10/2004	Hideo Ema	790086.405USPC	3862

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
05/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,343	EMA ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) *13-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/05,1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Sequence alignment 2070501_064405_us1-10-507-343-4.rpr.

DETAILED ACTION

This is the First Office Action on the Merits of the application filed 10 September 2004 as the U.S. national stage of international application PCT/JP02/02265, filed 11 March 2002. The preliminary amendment filed 18 April 2005 has been entered. Claims 1-86, as originally filed, are pending.

Election/Restrictions

Applicant's election of Group I (claims 1-12) in the reply filed on 9 February 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the 9 February reply.

Claim Objections

Claim 5 is objected to because of the following informalities: The claim sets forth sequence data without providing a corresponding SEQ ID NO. (See 37 CFR 1.821 (d), which states, "Where the description or claims of a patent application discuss a sequence that is set forth in the 'Sequence Listing' in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by 'SEQ ID NO:' in the text

of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.") Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, do not sufficiently distinguish over polypeptides and compositions as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. Specifically, given that polypeptides having WIF domains occur in nature, the claimed polypeptide and compositions comprising the polypeptide read on products of nature. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-9, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

In the instant case, the claims are directed to a polypeptide having a WIF domain wherein the polypeptide as the functional capacity to maintain pluripotency without differentiating a stem cell. In dependent claims the WIF domain is limited to comprising at least five amino acids among about position 30 to about position 180 of SEQ ID NO: 4, limited to comprising the sequence of about position 30 to about position 80 of SEQ ID NO: 4 or limited to comprising an EGF-like repeat. Beginning at page 27, the specification defines the term "WIF domain" as referring to an N-terminal region of the WIF-1 protein without the signal peptide thereof and extending until the EGF-like repeat starts. Furthermore, the specification teaches that the "WIF domain" will include sequences similar to the sequences of the WIF-1 WIF domain such as conservatively substituted variants or truncated WIF domains. Thus, the polypeptide of the claims embraces a broad and structurally divergent genus of molecules that encompasses any

protein comprising a "WIF domain", wherein the "WIF domain" as contemplated in the specification encompasses essentially unlimited variants[1] of the "WIF domain" found in WIF-1 polypeptides. Furthermore, the claims require that the polypeptide be capable of maintaining pluripotency without differentiating a stem cell.

In addition, the instant claim 11 is directed to a composition comprising a "stem cell survival agent", said "stem cell survival agent" is defined at page 31 as encompassing any agent considered to be essential for survival of a stem cell. Thus, the claim embraces a composition comprising any agent having the functional property of being essential for survival of a stem cell.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615.

In the instant case, the application discloses five species homologues of WIF-1 (see, e.g., Figure 1 and the caption thereto) and discloses WIF-1 polypeptides comprising conservative substitutions at 4 amino acid positions (two in the WIF domain; see especially Example 8, paragraph bridging pages 97-98). The specification demonstrates that the wild-type murine WIF-

[1] Note that claim 2 clearly evidences that the WIF domain of the invention is viewed as encompassing polypeptides having as little as 3% sequence identity with naturally occurring WIF domains.

1 polypeptide is capable of enhancing proliferation of hematopoietic stem cells in the presence of stem cell factor (SCF). (See especially Example 4, Tables 2 and 3.) The specification also teaches that WIF-1 proteins comprising the four conservative substitutions retained the capacity to enhance proliferation of hematopoietic stem cells in the presence SCF. However, given the vast scope of the structural variants within the scope of the claims, the few species of closely related polypeptides disclosed in the application fail to convey the necessary common attributes or features of the genus claimed.

With regard to the "stem cell survival agent" of claim 11, the application discloses the species of SCF, TPO, and flt-3 ligand. Clearly, however, these three species are not representative of a broad genus encompassing any agent considered to be essential for survival of any stem cell.

The written description requirement for a claimed genus may be satisfied through disclosure of the relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See MPEP §2163(3)(a)(ii)).

In the instant case, the disclosure provides no specific guidance beyond the species explicitly disclosed that would convey the relevant identifying characteristics of a broadly divergent genus of polypeptides having the function of maintaining pluripotency without differentiating a stem cell. It is noted that the claims encompass any polypeptide comprising the generic "WIF domain" of the claims, but there is no evidence that any polypeptide comprising, e.g., 5 amino acids of the sequence from about position 30 to about position 180 of SEQ ID NO:

4 (claim 2), would have the functional properties recited in the claims and there is no disclosure of which 5 amino acids correspond to the recited function. Although the disclosure provides some generic teachings related to modifying polypeptide sequences (pp. 34-38), the art teaches that the effect of modifying amino acid sequence on the function of a polypeptide is highly unpredictable. For example, Richards (1997) Cell Mol. Life Sci. 53:790-802 teaches, "[i]n terms of structural alterations and thermostability, responses to genetic mutations are context dependent and remain difficult to predict with any confidence" (abstract, column 1). Thus, Richards teaches that the effect of mutation on protein stability, a prerequisite for biological function, is unpredictable. Richards also teaches that even limited amino acid modifications can have dramatic effects on protein structure and function. In the second column on page 791, Richards cites the example of influenza virus hemagglutinin protein, wherein alterations in the ionization state of just a few ionizable groups dramatically alters the biological behavior of the molecule. Citing a published study of done on the gene V protein, Richards teaches that, in spite of only limited modification at two amino acid positions, "[t]he effects on the overall stability of the protein were remarkably variable" (page 794, column 1). In the paragraph bridging pages 796 and 797, Richards teaches, "[i]n single site mutants, the structural changes are generally greatest near the site of mutation, and moving away, decrease radially in all directions. Even the small changes are so complex that the linkage relations do not allow assignments of the energetic changes to unique parts of the altered residue and its immediate contacts" (emphasis added) and "[t]here is no convincing explanation yet of how the changes in binding can produce a major movement over such a distance." Finally, in the first full paragraph in the second column on page 793, Richards teaches, "[a]lmost all mutations are accompanied by some conformational change,

making prediction of the effects on stability difficult. In most cases mutations lead to lowering of the stability." (emphasis added). Thus, Richards teaches that small changes in the primary structure of a protein frequently have dramatic effects on the higher order structure and function of the protein, and that these effects are highly unpredictable.

Furthermore, the instant application teaches that the ability of WIF-1 polypeptides to enhance proliferation of hematopoietic stem cells in the presence SCF is dependent upon both the WIF domain and the EGF-like repeat domain of the WIF-1 protein. (See especially page 101, paragraph 4.) Thus, the presence of even the amino acid sequence from about position 30 to about position 180 of the sequence set forth as SEQ ID NO: 4 does not reliably identify a protein as having the ability to enhance proliferation of hematopoietic stem cells in the presence SCF.

With regard to the "stem cell survival agent" of claim 11, the disclosure provides no guidance as to the characteristics that identify any given agent as a stem cell survival agent beyond the disclosure of three explicitly named species. Thus, the stem cell survival agent of the claims is a product identified solely by the function of the product. However, a definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." Eli Lilly, 119 F.3 at 1568, 43 USPQ2d at 1406. See also Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)).

Although the specification discloses methods by which one might identify compounds having the activities of the claimed compounds, an adequate written description of a compound requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the compound itself. It is not

sufficient to define a compound solely by its principal biological property because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any compound with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all polypeptides and agents that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of claimed polypeptides and agents. Therefore, only the explicitly disclosed species meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsieh et al. (1999) *Nature* 398:431-436 (made of record in the IDS filed 2 February 2005).

The claims are directed to a polypeptide having a WIF domain which maintains pluripotency without differentiating a stem cell and a composition comprising said polypeptide.

The claims identify a polypeptide comprising SEQ ID NO: 4 as a species of the invention. (See claim 6.) Hsieh teaches a polypeptide that is 100% identical to the instant SEQ ID NO: 4 (see Figure 1 and the attached sequence alignment 2070501_064405_us1-10-507-343-4.rpr) and a composition comprising said polypeptide (i.e., conditioned serum-free medium; see especially page 435, right column, fourth full paragraph). As the polypeptide of Hsieh et al. is structurally identical to the polypeptide of the claims, it is reasonable to presume that the functional properties recited in the claims are inherent to the polypeptide.

The polypeptide and composition of Hsieh et al. is the same as the polypeptide and composition claimed in the instant application; therefore the claims are anticipated by Hsieh et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al. (*supra*) in view of Racher et al. (1995) *Biotechnol. Techniques* 9:169-174.

As described above, Hsieh et al. teaches a composition of serum-free medium comprising a WIF-1 polypeptide comprising the sequence set forth as SEQ ID NO: 4. Hsieh et al. teaches that the composition was produced by conditioning serum-free medium on cultured 293 cells transfected with a nucleic acid encoding the WIF-1 polypeptide. Hsieh et al. does not teach that the composition comprises a stem cell survival agent.

Racher et al. teaches that 293 cells are cultured in DMEM containing glucose. (See especially the second full paragraph on page 170.)

It would be obvious to one ordinary skill in the art to use the culture medium base of DMEM and glucose taught by Racher et al. to make the composition comprising a WIF-1 polypeptide as taught by Hsieh et al. One would be motivated to use the DMEM and glucose composition because it was known in the art to support the survival of 293 cells. One would have a reasonable expectation of success in combining these teachings because there is no reason to

expect that serum free DMEM containing glucose could not be used to obtain conditioned medium.

Given the broadly generic definition of "stem cell survival agent" as including any agent considered to be essential for survival of a stem cell, the skilled artisan would reasonably conclude that agents such as glucose and other components of culture media that are essential for survival of any cell, including stem cells, are within the scope of "stem cell survival agents". Therefore, the method of Hsieh et al. in view of Racher et al. would provide a medium comprising all of the elements of the claimed composition. Thus, the composition of the instant claim 11, as a whole, would have been obvious to one of ordinary skill in the art at the time the instant invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

2070501_064405_us1-10-507-343-4.rpr

RESULT 1
A59180
Wnt inhibitory factor-1 - human
C;Species: Homo sapiens (man)
C;Date: 18-Feb-2000 #sequence_revision 18-Feb-2000 #text_change 09-Jul-2004
C;Accession: A59180
R;Hsieh, J.C.; Kodjabachian, L.; Rebbert, M.L.; Rattner, A.; Smallwood, P.M.; Samos, C.H.; Nusse, R.; Dawid, I.B.; Nathans, J.
Nature 398, 431-436, 1999
A;Title: A new secreted protein that binds to Wnt proteins and inhibits their activities.
A;Reference number: A59180; MUID:99215557; PMID:10201374
A;Accession: A59180
A;Status: preliminary; not compared with conceptual translation
A;Molecule type: mRNA
A;Residues: 1-379 <HSI>
A;Cross-references: UNIPROT:Q9Y5W5; UNIPARC:UPI0000051058; GB:AF122922; NID:g4585369; PIDN:AAD25402.1; PID:g4585370

Query Match 100.0%; Score 2148; DB 2; Length 379;
Best Local Similarity 100.0%; Pred. No. 5.5e-143;
Matches 379; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Db        361 PSLKKAEERRDPPESNYIW 379
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Daniel M Sullivan, Ph.D.
Primary Examiner
Art Unit 1636